



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

*Certification Association "Russian Register" has issued an IQNet recognized certificate that the organization:*

## **LLC "Zavod Medsintez"**

*including production sites in the Annex  
28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia*

*has implemented and maintains a*

### **Quality Management System**

*for the following scope:*

development, launching into manufacture, preparing for manufacture, manufacture, storage and marketing of medical devices: active and non-active devices for injection, infusion, dialysis, artificial circulation and hemapheresis; non-active devices for cleaning, rinsing, preparation of solutions; protective equipment made of nonwoven materials

*which fulfils the requirements of the following standard:*

## ISO 13485:2016


*Issued on: 6<sup>th</sup> October, 2021*

*Expires on: 30<sup>th</sup> August, 2023*

*This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document*

**Registration Number: RU-20.1001.026**



  
*Alex Stoichitoiu*  
*President of IQNet*

  
*Arkady Vladimirtsev,*  
*Director General of*  
*Russian Register*



**IQNet Partners\*:**

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## **ANNEX 1 to IQNet Certificate**

**Number RU-20.1001.026**

### **Certification scope of management system of LLC "Zavod Medsintez"**

1. Product / service: development, launching into manufacture, preparing for manufacture, manufacture, storage and marketing of medical devices: active and non-active devices for injection, infusion, dialysis, artificial circulation and hemapheresis; non-active devices for cleaning, rinsing, preparation of solutions; protective equipment made of nonwoven materials.
2. Processes of product realization in compliance with ISO 13485:2016:
  - 7.1. Planning of product realization
  - 7.2. Customer-related processes
  - 7.3. Design and development
  - 7.4. Purchasing
  - 7.5. Production and service provision
  - 7.6. Control of monitoring and measuring equipment
3. Exclusions from the processes of product realization: 7.3.6 и 7.3.7 (in terms of connection with another medical device(s) or availability of a common interface); 7.5.1 f) (in terms of post-delivery activities); 7.5.2 (except of distilled water); 7.5.3; 7.5.4; 7.5.9.2; 7.5.10; 8.2.6 (in terms of implantable medical devices); 8.4f.



  
 Alex Stoichitoiu  
 President of IQNet

  
 Arkady Vladimirtsev,  
 Director General of  
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**ANNEX 2 to IQNet Certificate**  
**Number RU-20.1001.026**

**Certification scope of management system of  
LLC "Zavod Medsintez" includes:**

**1. Workshop No. 1**

Legal address: 28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia

Actual address: 15, Torgovaya Str., 624130, Novouralsk, Sverdlovsk region, Russia

**2. Workshop No. 2**

Legal address: 28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia


Actual address: 15, Torgovaya Str., Bldg. 3, 624130, Novouralsk, Sverdlovsk region, Russia

**3. Workshop No. 11**

Legal address: 28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia

Actual address: 9, Podgornaya Str., 624130, Novouralsk, Sverdlovsk region, Russia



  
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